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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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Additional inventors are being named on the ________ *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

USING A RADIOACTIVE SOURCE AS THE TRACKED ELEMENT OF A TRACKING SYSTEM

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Respectfully submitted,

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Date 6 SEPTEMBER 2004

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Utilizing a radioactive source as the tracked element for a tracking system

Provisional Patent

Written by:
Shlomi Ben-ari

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1. Scope

This application provides a description of a novel medical tracking technology based on utilizing a radioactive source as the tracked element. It is written in order to be submitted as a provisional patent.

2. Background

In many minimally invasive medical procedures, the operator navigates the medical tool to the required location within the body. Knowledge of the exact location of the medical tool is essential for the navigation process.

Existing techniques for tracking small medical tools within the body (e.g. catheter tip) include:

- Fluoroscopy (perform the procedure under X-Ray imaging)
- Electro Magnetic tracker
- Optical tracker

2.1. The medical need

The identified need is a system that tracks the location of a medical tool (such as a catheter tip, needle, laparoscopic tool, etc.) within the body.

This system is referred to as a Tracking system.

2.1.1. Required tracking system characteristics

- Provide 3 dimensional position tracking of a small element
    - Tracked element size: 0.1 to 1 mm diameter, Goal: below 0.3 mm
- Does not expose the patient or the operator to harmful doses of radiation
- Accurate tracking - less than 1 mm error, in the harsh environment of standard operating arena
    - In presence of metal objects and tools
    - EM Radiation emitted by medical equipment
- Does not require clear line of sight to the tracked element
- Does not require rigid connection between the tracked element and the outside world
    - To allow intravascular procedures
- Wireless tracked element is preferred

2.2. Prior art medical tracking solutions

2.2.1. Fluoroscopy

Most minimally invasive surgical tools, including catheters and guide wires, are visible in X-ray fluoroscopic images. This is the standard method of navigating catheters and guide wires during catheterization procedures. The major disadvantage of using X-ray fluoroscopy for the purpose of navigation within the body is that it exposes both the patient and the doctor to large doses of harmful radiation.

2.2.2. Electro Magnetic Tracker

Most of the existing intravascular tracking systems are based on Electro Magnetic (EM) tracking technology. The EM tracker is based on generating a quasi static magnetic field within the volume of interest. The tracked element senses the field in its vicinity and its location is calculated based on its measurement of the local field.

EM tracker disadvantages:

- The EM tracker is vulnerable to Electro Magnetic Interference (EMI) emmited from PC monitors and other medical equipment.
- The EM tracker accuracy is degraded due to metallic objects in the vicinity of the tracker.
- Tracking the tip of a catheter requires routing wires along the catheter.

2.2.3. Optical Tracker

Optical tracking is based on analyzing images from a number of cameras viewing the tracked element (Light source or Reflector).

Optical Tracker disadvantages:

- Applicable only to situations where the tracked element is rigidly attached to a visible light source or reflector. Thus it is not applicable to intravascular navigation
- Requires a clear path from the cameras to the tracked element.

3. The proposed solution for an IV tracking system

3.1. Concept overview

The proposed tracking solution is to use a radioactive source (gamma ray emitter) as the tracked element. The radioactive source is installed on the tip of the medical tool.

Its location within the body is calculated based on samples of the radiation measured outside the body in several locations.

This patent deals with any implementation of a tracker (or navigation system) that is based on tracking the position of a radioactive element. However, following is a description of a specific implementation method of such a tracking system. This description is provided as an example and feasibility proof of the concept.

3.2. Tracker Implementation example

One example of a radioactive tracker concept is to utilize a set of tracking modules. Each tracking module provides one angle defining a plane within which the tracked element lies. By combining the information from several modules at different locations, the system can accurately calculate the location of the radioactive element in three dimensions.

The following section provides a bottom up description of the tracking system, starting with the basic tracking modules and from there to the system level concepts.

3.2.1. Basic Tracking Module (BTM)

Radioactive matter emits particles in random directions. The basic gamma ray sensors can not detect the origin of the radiation i.e. the direction of the ray is unknown. One way in which the sensor can become direction-sensitive is by installing a collimator on top of it. By doing so, most of the radiation is obscured and thus, the sampling time is increased substantially.

The proposed solution implements a differential sensor, and thus, one can determine the direction to the radiation source about one axis without obscuring the majority of the incoming radiation (allowing for short sampling time).

3.2.1.1. BTM Structure

Following is a conceptual view of the Basic tracking module.

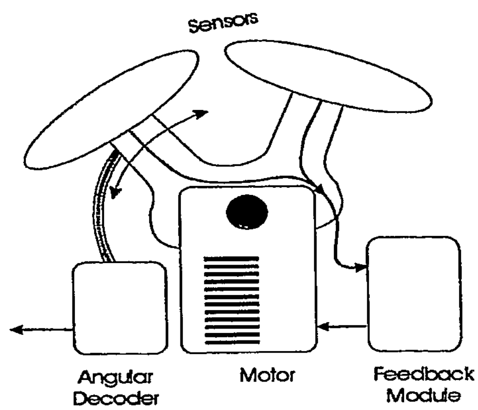

Figure 1 : Basic Tracking Module – conceptual view

The Basic Tracking Module (referred as BTM) is composed of the following:

- 2 radiation detectors.
  Geometrically arranged such that the ratio between their readings is sensitive to the relative location of the radiation source (in at least one axis)
- Moving mechanical mount that can rotate (or translate) the above sensors.
- Feedback mechanism.
  The function of this module is to rotate (or translate) the sensors until their readings are identical. Digital or Analog Signal processing may be utilized for this purpose.
- Orientation (or position) decoder.
  The function of this device is to measure the actual orientation (or position) of the sensors in which the readings are identical.

3.2.1.2. BTM Functionality

The BTM output is the angle (about the axis of the BTM) from the BTM to the radiator.

3.2.1.3. Differential gamma sensor arrangement

Following is an example of a gamma ray differential sensor:

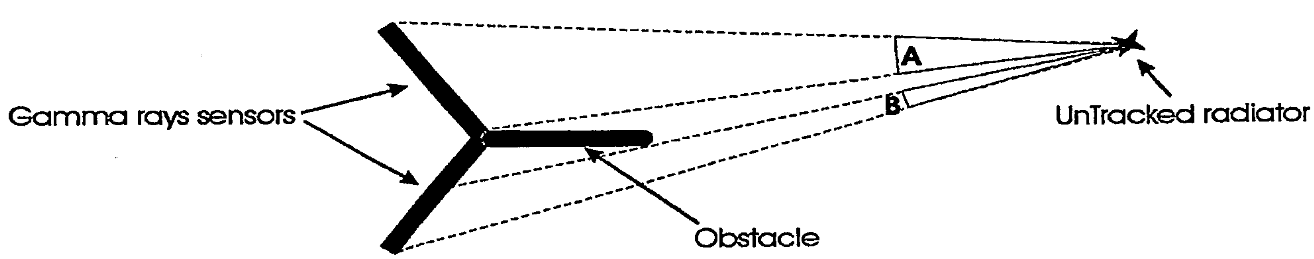

Figure 2 : Nuclear differential sensor

Since the radiation is emitted randomly, the number of particles that are sensed by each sensor is proportional to the spatial angle of the sensor, as viewed from the emitter.
For example, in Figure 2, the red sensor will detect more particles per unit time than the blue sensor, since angle A is larger than B. (assuming enough data is accumulated to overcome the quantization noise)
Only when the sensor is pointing directly at the emitter, will the two readings be identical.
The sensors can be rotated until the particle hit rate is identical for the two sensors. Mechanical measurement of the sensor's orientation in this situation provides the angle from the sensor to the emitter about the axis of rotation of the sensor.

3.2.2. Tracker System

The tracker system's objective is to calculate the position of the tracked element (radiator).

Following is a schematic illustration of such a system:

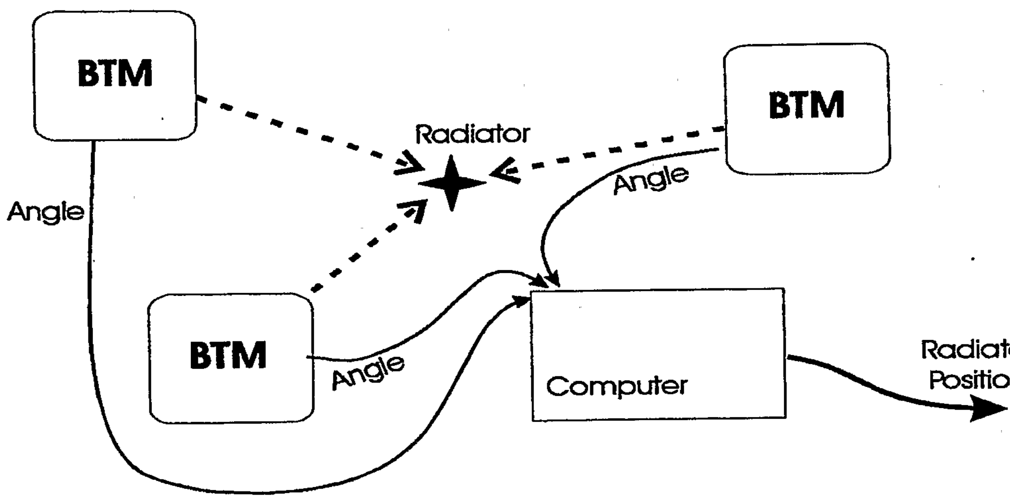

Figure 3 : Tracker system structure

The tracking system is composed of several Basic Tracking Modules (BTMs), each providing the angle from it to the radiator about one axis.
Knowing the position and axis orientation of all of the BTMs in the system, one can calculate the radioactive element position in space relative to the BTMs.
Each BTM output defines a plane in which the radiator resides; this plane is defined by the measured angle. It is known that the intersection of three planes defines a single point in space.
Thus, a system comprised of three BTMs is able to locate the radiator.
If more than three BTMs are installed, it is possible to improve the overall accuracy and to provide a Figure of Merit along with the position (FOM - estimation of the tracking error).

3.2.3. Tracker implementation example

3.2.3.1. Tracker refresh rate

- The tracker calculates the location of the emitter at 10 Hz (every 100 mSec)

3.2.3.2. Geometry

- Distance between sensor and radiator: 10 to 40 cm

3.2.3.3. Sensor dimensions

- Each element of the differential sensor is 3*6 cm
- The sensor geometry shall be designed to maximize the angular sensitivity i.e. maximize the difference between the two sensors' output resulting from an angular change

3.2.3.4. Radioactive source attributes

- Radiation: 1 mCi
- Energy: 250-600 KeV

3.2.4. Tracker accuracy analysis

Following is an abbreviated analysis that calculates the tracker system performance. This analysis proves the feasibility of such a system.

3.2.4.1. Number of photons that hit each sensor (per sample)

- 1 mCi = $3.7*10^7$ Disintegrations Per Second
- Which is ~ 3200 Counts / cm^2 / Second @ 30 cm { $3.7*10^7/(4piR^2)$ }
- An attenuation coefficient of ~ 0.1/cm results in ~ 88% absorption through 20cm of tissue leaving ~ 384 Counts / cm^2 / Second @ 30 cm
- Each sensor area is 18 cm^2 placed in 45 degrees (pointing at the emitter) → effective area is ~12.5 cm^2.

  The sampling time is 100 mSec.

  Thus, on average each sensor will count about 480 hits per tracker cycle.

3.2.4.2. Angular error (jitter)

A computer simulation was implemented in order to estimate the angular error of such a sensor. The simulation is based on the following assumptions:

- sensor size, sampling time, radioactive activity, and radiation attenuation are as described above
- 5cm high wall dividing the two elements of the differential sensor
- ignoring signal from scatter
- assuming that the dividing wall blocks all radiation and that the sensors absorb 50% of the radiation that hits their surface

Simulation results:

- **The results of the simulation indicate that the expected RMS position error along the direction perpendicular to the axis of the sensor at a distance of 30cm is approximately 0.5mm**

3.2.4.3. Position calculation error

Assuming that the system is composed of 4 angular sensors, each with an RMS error of 0.5mm, the resulting 3-dimensional position error will be ~0.87mm